

REMARKS

Independent Claim 7 has been amended. Claim 9 has been canceled. New independent claim 25 has been added. Dependent claims 8 and 10 to 21 have been amended to be multiple dependent upon claim 7 and new claim 25, as well as attending to correcting certain typographical matters. New dependent claims 22 to 24 have been added.

New independent claim 26 and dependent claims 27 to 32 have been added.

Claims 7, 8, and 10 to 32 remain in the application. Of these, method claim 7, method claim 25, and method claim 26 are the independent claims.

The Examiner's time and attention at the interview conducted September 15, 2004 is acknowledged and appreciated. During the interview, co-inventor Karen Talmadge discussed the vertebral fractures and their serious health consequences; prior art techniques for their treatment by pain management (medication), external bracing, and major surgery (spine fixation); and the development of the methodology disclosed in Scholten US 5,108,404. It was pointed out that Scholten '404 discloses full or entire expansion of an expandable body within the space bounded by the cortical walls of the vertebra. Karen Talmadge addressed the later, unexpected, and surprising discovery by her and her co-inventors that the technique of Scholten could be accomplished by an expandable body that did not maximally compact cancellous bone -- that is, by using an expandable body that, when fully expanded within the vertebra, occupies less the entire interior volume of the vertebra. Karen Talmadge, also explained the unexpected benefits of using of an expandable body that, when fully expanded within the vertebra, occupies less the entire interior volume of the vertebra -- for example, interdigitation of bone filler into the cancellous bone, preventing undesired bone movement, and keeping as much healthy cancellous bone intact (uncompacted) as possible. Karen Talmadge also discussed the significant commercial success of the procedure, now widely called Kyphoplasty, in terms of documented clinical results, public recognition, and revenue growth for Kyphon Inc. (the company to which the instant application is assigned).

At the interview, the Examiner indicated that the claims should be amended to include language defining the interior volume of cancellous bone in relation to the dimensions of the expandable body. The accompanying amendments to the claims are believed to address the Examiner's request.

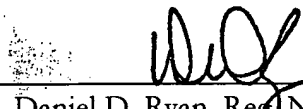
Claim 7 has been amended to define an expandable region that creates a void in cancellous bone by assuming a predetermined shape and size when substantially expanded within a vertebral body including (i) an anterior-to-posterior dimension that is less than an anterior-to-posterior anatomic measurement between interior cortical walls from an anterior cortex to a posterior cortex of the vertebra, or (ii) a side-to-side dimension that is less than a side-to-side anatomic measurement between internal cortical walls laterally across the vertebral body, or both (i) and (ii), and, further, that this void is filled with a filling material. New claim 25 includes this terminology, but does not include the stress-related terminology found in claim 7. New claim 26 defines the expansion of an expandable portion of a tool within the vertebra to define a bounded volume bounded, at least in part, by a boundary having an inner layer and an outer layer, the inner layer including compacted cancellous bone, the outer layer including noncompacted cancellous bone, and, further, that this bounded volume is filled with a filling material. Support for the terminology in the amended and new claims can be found, e.g., on Specification pages 17 and 18.

The Examiner's attention is directed to the Supplemental Information Disclosure Statement that accompanies this amendment. The Statement lists documents that have been brought to the attention of the applicant by a third party in the course of infringement litigation involving Scholten US 5,108,404 and US 4,969,888 (same disclosure as US 5,108,404); Reiley et al US 6,235,043 (listed in the Supplemental Information Disclosure Statement and as to which the instant case claims CIP status from the parent application 08/188,224 (Now Abandoned)); and Reiley et al US 6,248,110 (listed in the attached Supplemental Information Disclosure Statement and as to which the instant case claims CIP status from the parent application 08/188,224 (Now Abandoned)). These additional documents (listing in the attached Supplemental Information Disclosure Statement) are: US 4,653,489; US 4,369,772; US 4,432,358; US 3,997,138; US 4,772,287; US 3,626,949; US 5,127,912; US 4,987,892; ; and Kunec, J.R., et al., Closed Intramedullary Rodding of Pathologic Fractures with Supplemental Cement, Clinical Orthopaedics and Related Research, vol. 188, pp. 183-86 (Sept. 1984). These documents are not believed to teach or suggest the subject matter defined in the amended claims, but are nevertheless being listed in the Supplemental Information Disclosure Statement in interest of full disclosure.

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Allowance of claims 7, 8, and 10 to 32 is respectfully requested.

Respectfully Submitted,

By  _____
Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.
Post Office Box 26618
Milwaukee, Wisconsin 53226
(262) 783 - 1300
Customer No.: 26308